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(54) **BODY ADHERENT PATCH WITH ELECTRONICS FOR PHYSIOLOGIC MONITORING**

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See application file for complete search history.

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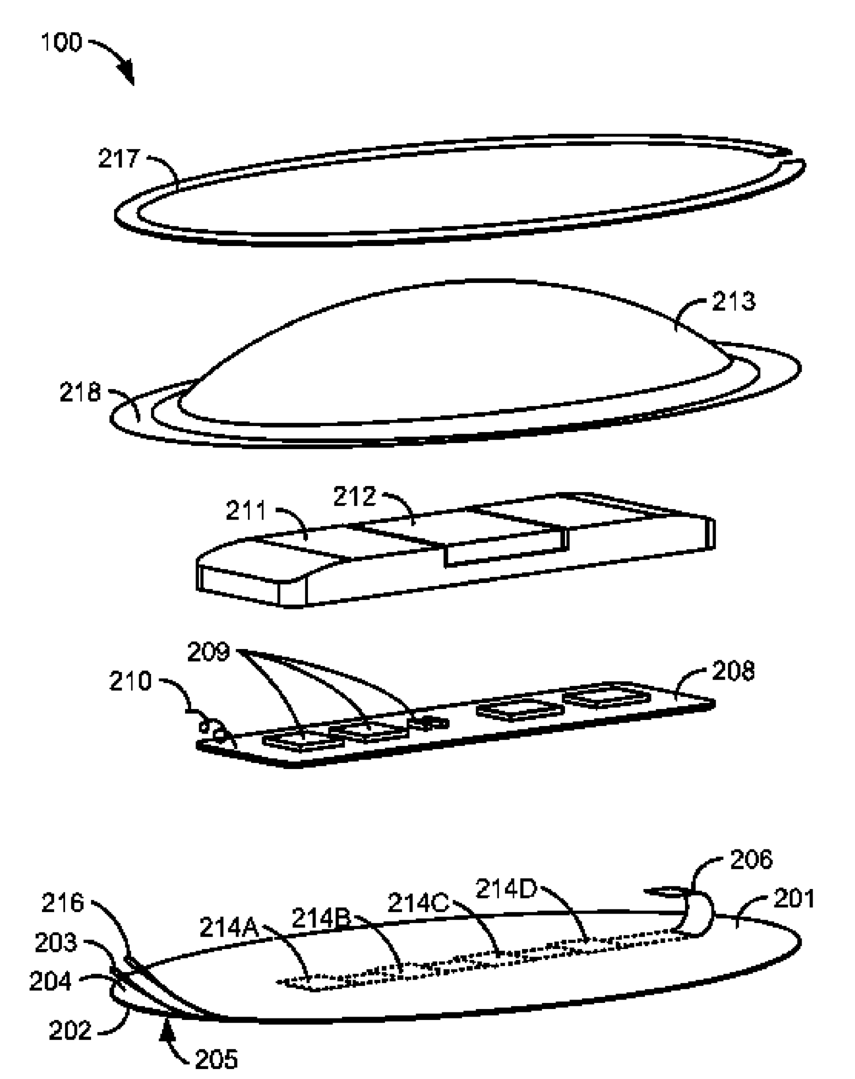
(57) **ABSTRACT**

In one configuration, an adherent device to adhere to a skin of a subject includes a stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side to adhere the base layer to the skin of the subject. The base layer has at least two openings extending therethrough, each of the at least two openings having a size. The adherent device also includes a stretchable covering layer positioned above and adhered to the base layer with an adhesive to define at least two pockets. The adherent device also includes at least two gels, each gel having a size larger than the size of openings to retain the gel substantially within the pocket, and a circuit carrier supported with the stretchable base layer to measure at least one physiologic signal of the subject. Other configurations and methods are also claimed.

21 Claims, 7 Drawing Sheets



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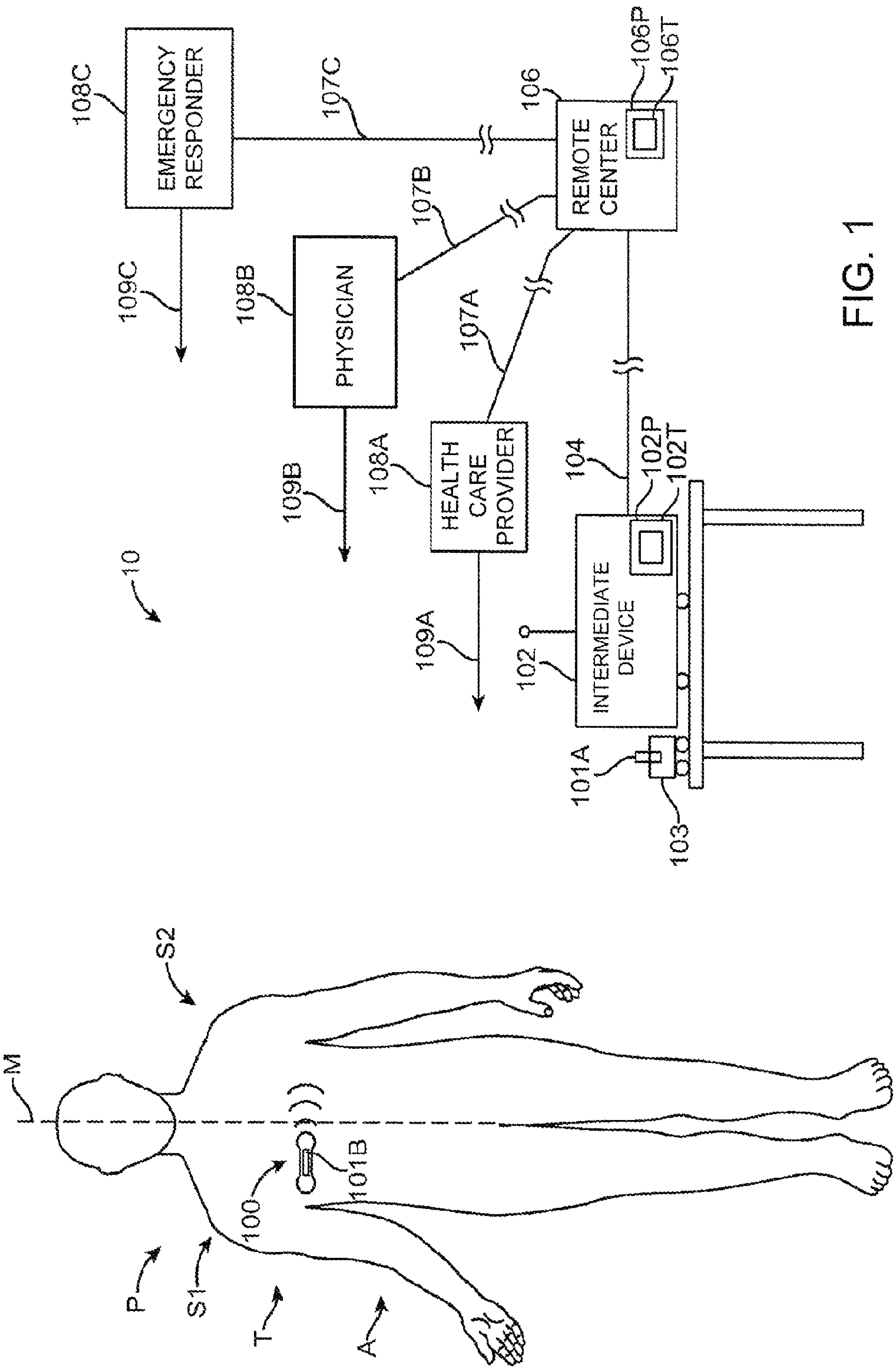
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FIG. 1

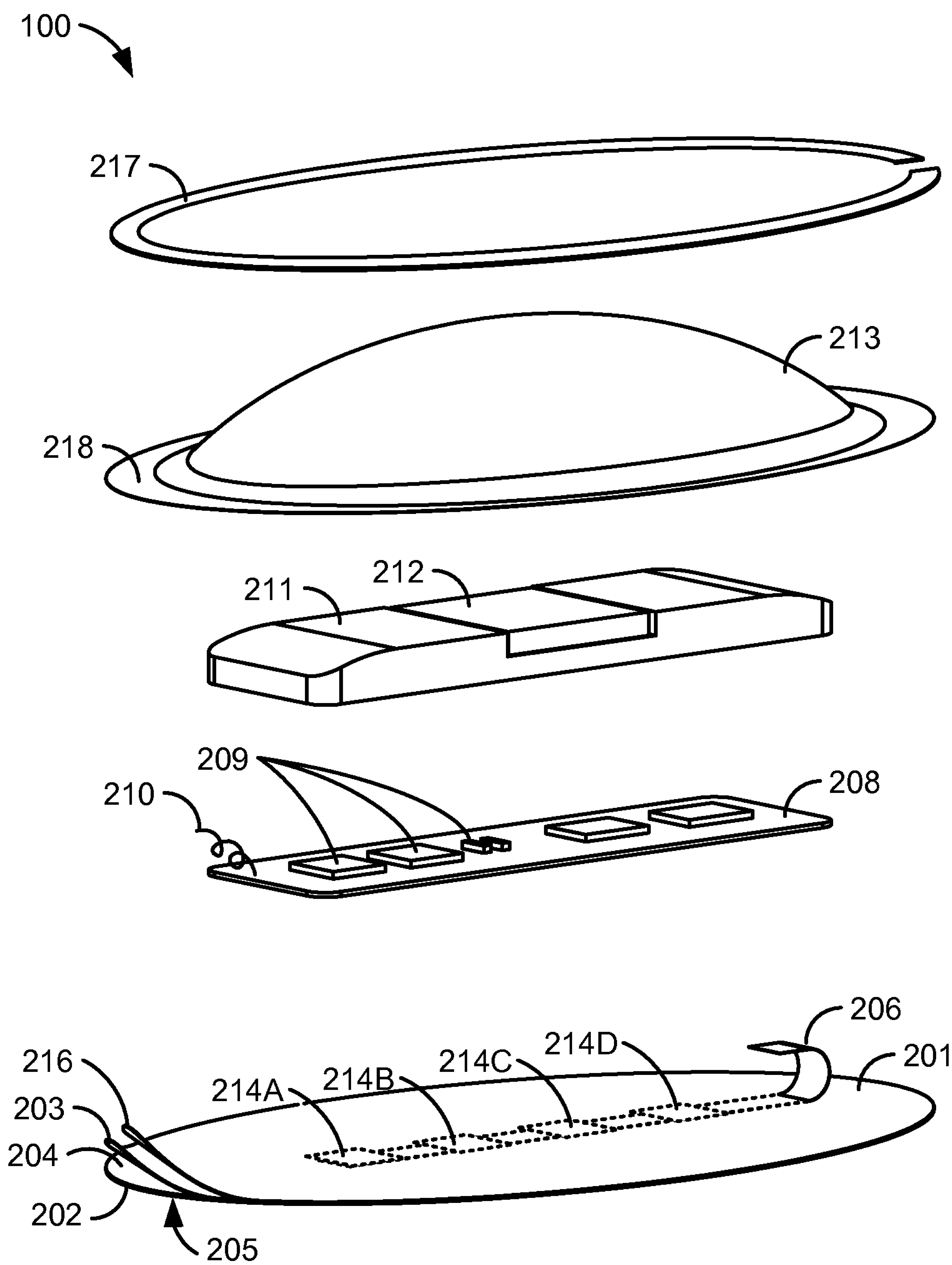
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FIG. 2A

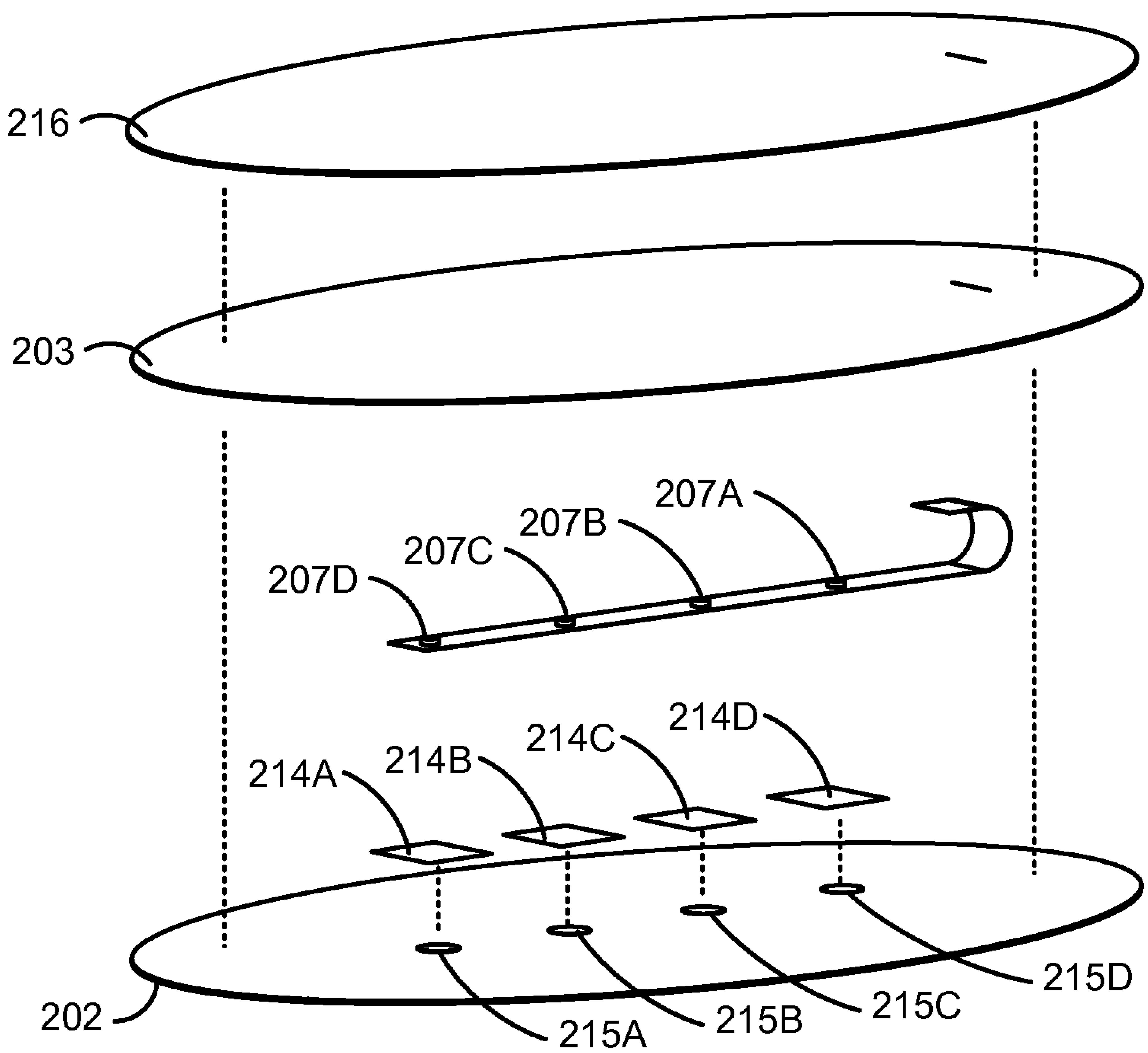
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FIG. 2B

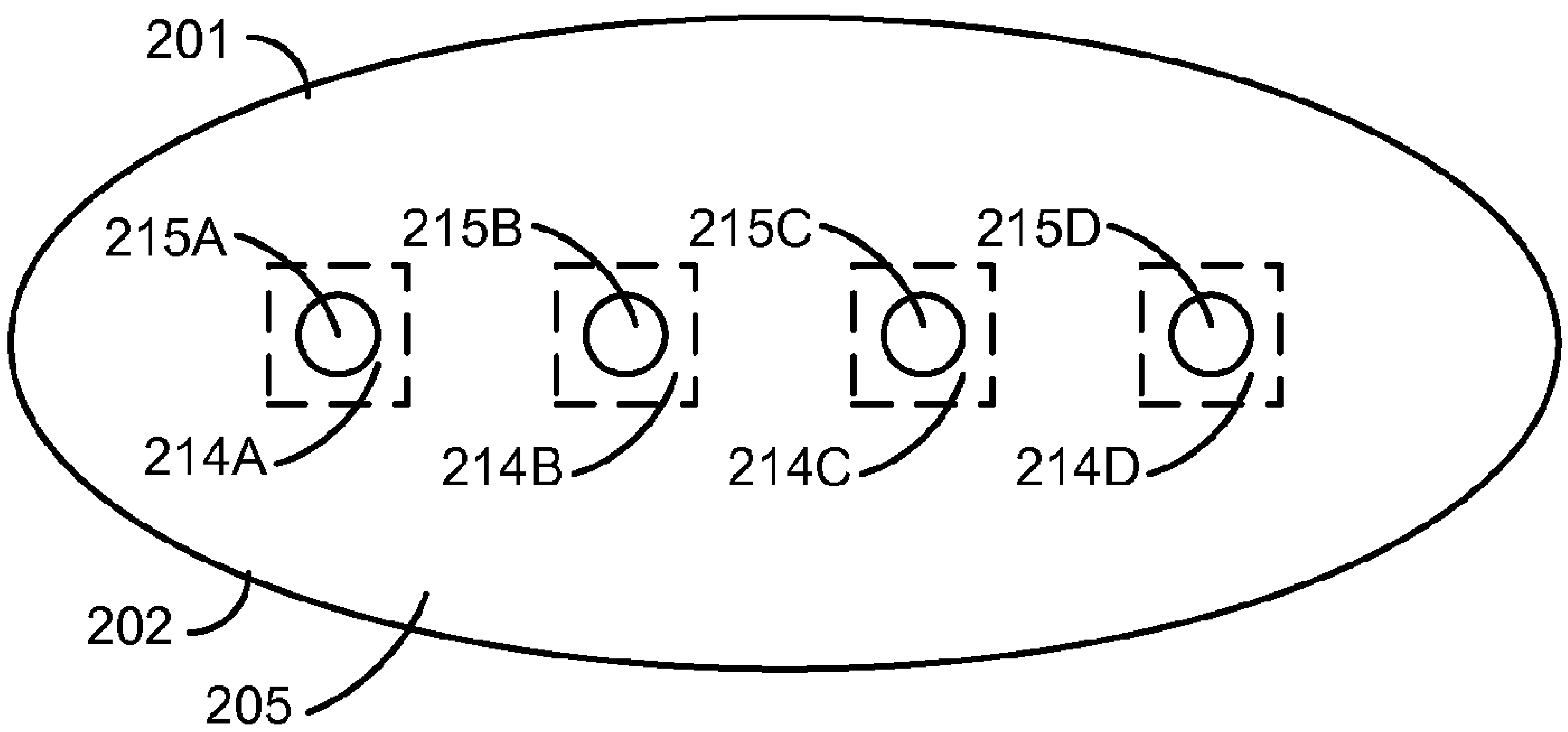
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FIG. 2C

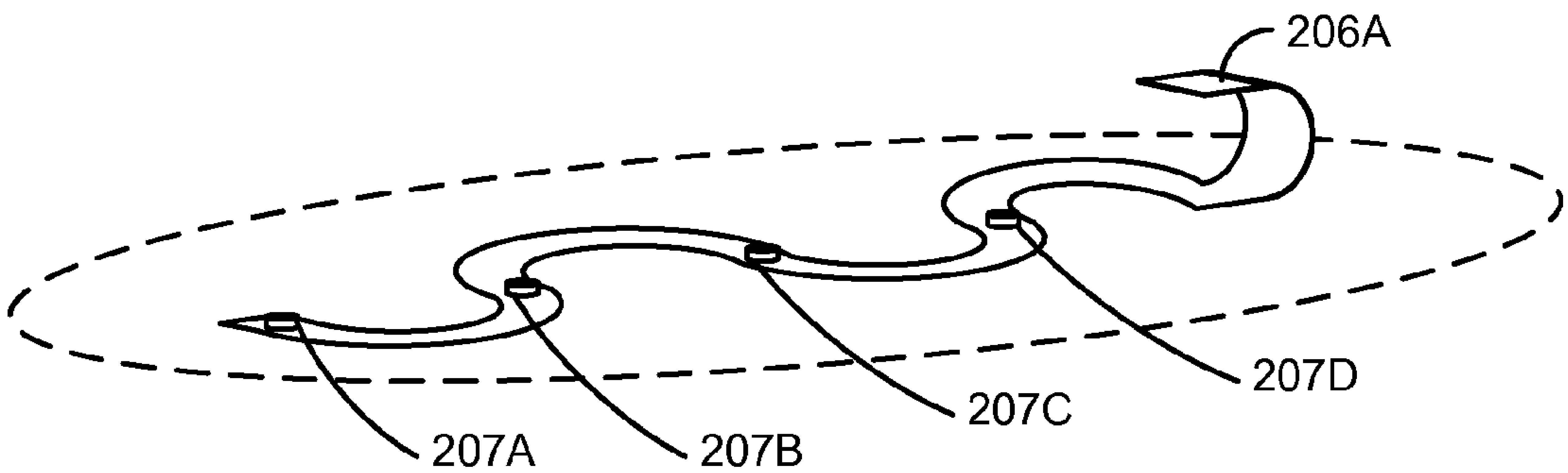
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FIG. 3

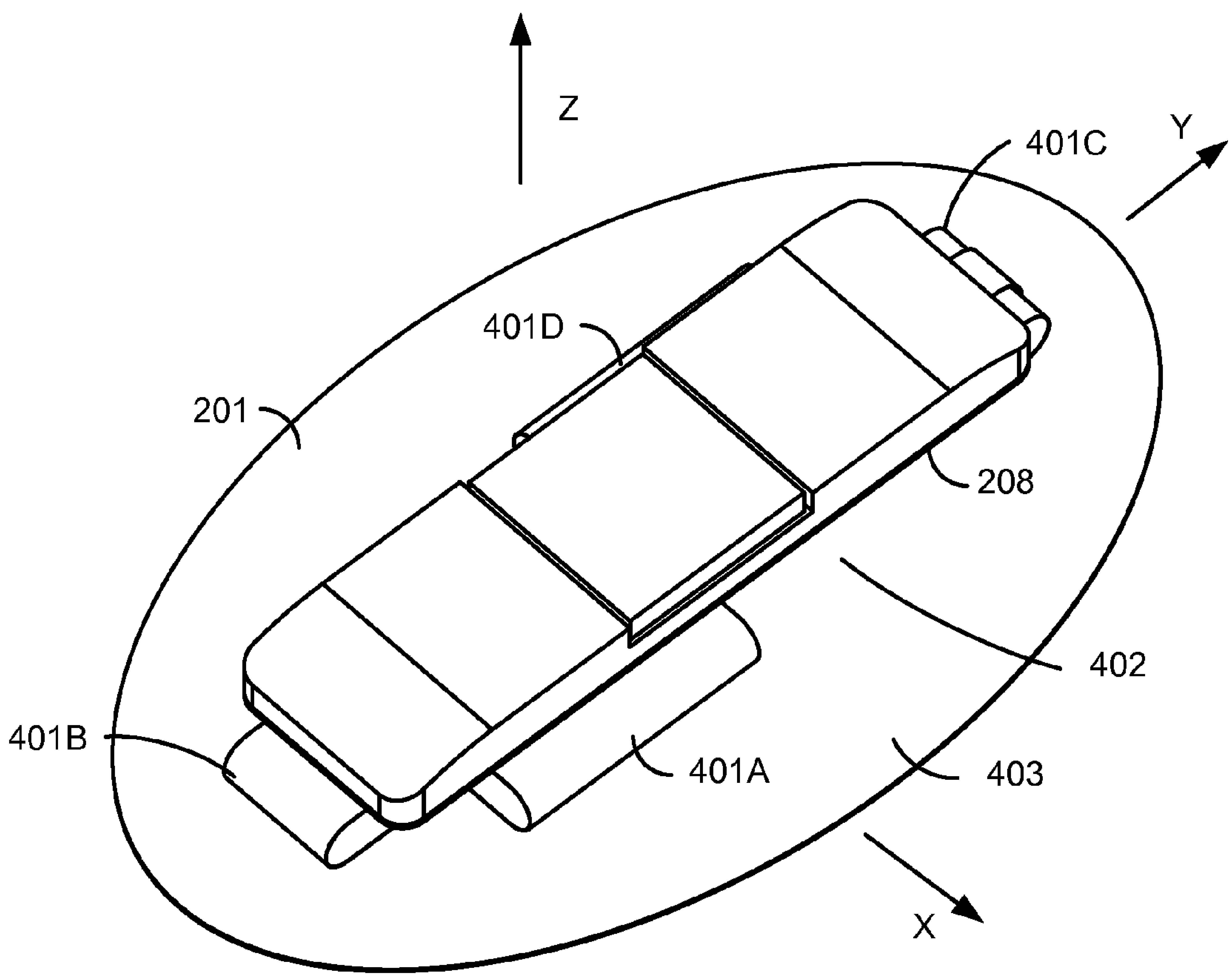

FIG. 4

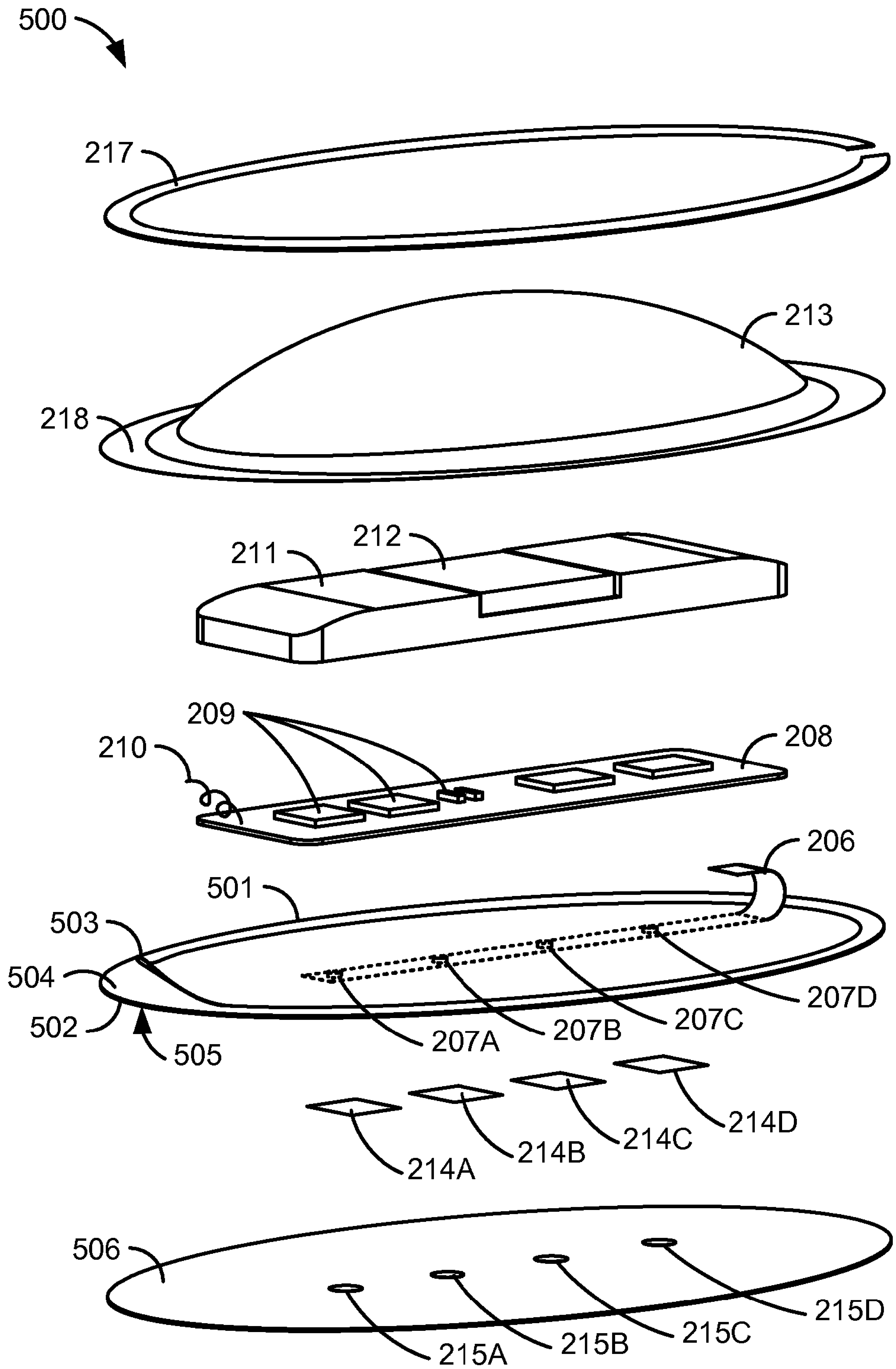
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FIG. 5

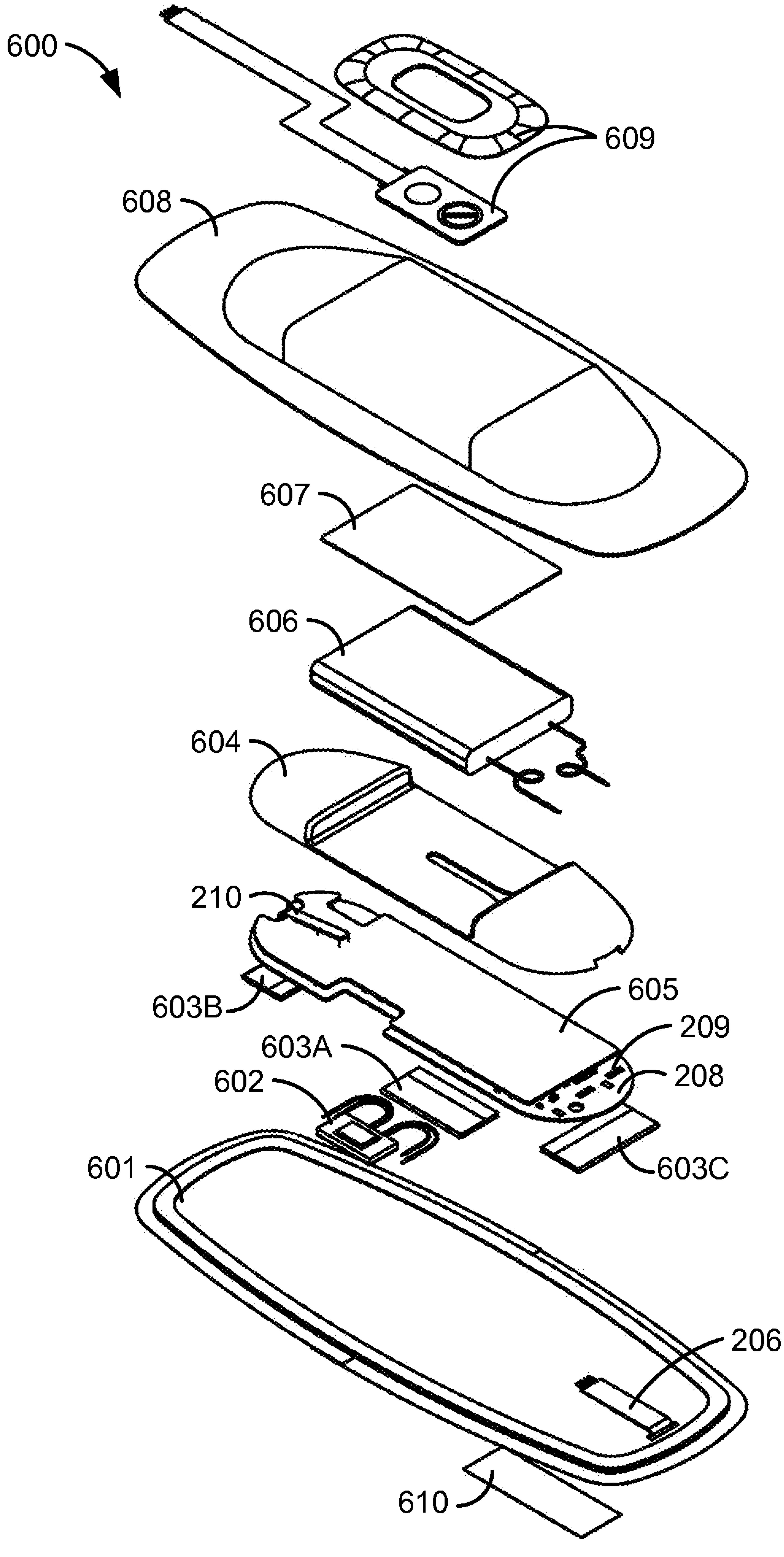
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FIG. 6

BODY ADHERENT PATCH WITH ELECTRONICS FOR PHYSIOLOGIC MONITORING

This application claims priority from provisional U.S. Patent Application No. 61/286,075, titled "Body Adherent Patch with Electronics for Physiologic Monitoring" and filed Dec. 14, 2009, the entire disclosure of which is hereby incorporated by reference herein for all purposes.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to physiologic monitoring and/or therapy. Although embodiments make specific reference to monitoring impedance and electrocardiogram signals with an adherent device, the system methods and devices described herein may be applicable to many applications in which physiological monitoring and/or therapy is used for extended periods, for example wireless physiological monitoring for extended periods.

Patients are often treated for diseases and/or conditions associated with a compromised status of the patient, for example a compromised physiologic status. In some instances, a patient may report symptoms that require diagnosis to determine the underlying cause. For example, a patient may report fainting or dizziness that requires diagnosis, in which long term monitoring of the patient can provide useful information as to the physiologic status of the patient. In some instances a patient may have suffered a heart attack and require care and/or monitoring after release from the hospital. One example of a device to provide long term monitoring of a patient is the Holter monitor, or ambulatory electrocardiography device.

In addition to measuring heart signals with electrocardiograms, known physiologic measurements include impedance measurements. For example, transthoracic impedance measurements can be used to measure hydration and respiration. Although transthoracic measurements can be useful, such measurements may use electrodes that are positioned across the midline of the patient, and may be somewhat uncomfortable and/or cumbersome for the patient to wear. In at least some instances, the electrodes that are held against the skin of the patient may become detached and/or dehydrated, such that the electrodes must be replaced, thereby making long term monitoring more difficult.

Work in relation to embodiments of the present invention suggests that known methods and apparatus for long term monitoring of patients may be less than ideal. In at least some instances, devices that are worn by the patient may be somewhat uncomfortable. Although devices that adhere measurement electrodes and measurement circuitry to the skin with an adhesive can provide improved comfort, work in relation to embodiments of the present invention suggests that the adhesive of such devices can detach from the skin of the patient sooner than would be ideal. These limitations of current devices may lead to patients not wearing the devices as long as would be ideal and not complying with direction from the health care provider in at least some instances, such that data collected may be less than ideal.

Similar difficulties may arise in the monitoring of other subjects, such as persons in non-medical settings, or in the monitoring of animals such as veterinary, agricultural, or wild animal monitoring. Therefore, a need exists for improved subject monitoring. Ideally, such improved subject monitoring would avoid at least some of the shortcomings of the present methods and devices. Ideally, such improved devices will allow an adherent device to be adhered to the skin of the subject with an adhesive so as to carry associated electronics comfortably with the skin of the subject for an extended period.

2. Description of the Background Art

The following U.S. Patents and Publications may describe relevant background art: U.S. Pat. Nos. 3,170,459; 3,805,769; 3,845,757; 3,972,329; 4,141,366; 4,522,211; 4,669,480; 4,838,273; 5,133,355; 5,150,708; 5,450,845; 5,511,533; 5,607,454; 6,141,575; 6,198,955; 6,327,487; 6,795,722; 7,395,106; 2004/0006279; 2004/0015058; 2006/0264730; 2007/0106132; 2007/0208262; 2007/0249946; 2007/0255184; 2008/0171929; 2007/0276273; and 2009/0182204.

BRIEF SUMMARY OF THE INVENTION

In many embodiments, an adherent device to adhere to a skin of a subject comprises a stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side to adhere the base layer to the skin of the subject. The base layer has at least two openings extending therethrough, each of the at least two openings having a size. The adherent device also comprises a stretchable covering layer positioned above and adhered to the base layer with an adhesive to define at least two pockets, and at least two gels, each gel having a size larger than the size of the at least two openings to retain said gel substantially within said pocket. The adherent device further comprises a circuit carrier supported with the stretchable base layer to measure at least one physiologic signal of the subject. The subject may comprise a person, an athlete, a patient, or an animal such as a domesticated or a wild animal.

According to some embodiments, an adherent device to monitor a subject having a skin comprises a stretchable base layer having an upper side and a lower side and an adhesive coating disposed on the lower side to adhere the base layer to the skin of the subject. The base layer has at least two openings extending therethrough, each opening having a size. The adherent device further includes a flexible circuit support having at least two electrodes disposed thereon, each electrode positioned with a respective one of the at least two openings to couple to the skin of the subject. At least two gels are positioned with the at least two openings in the base layer, each gel having a size larger than the size of said each opening. The device also includes a stretchable covering layer positioned above the at least two gels and adhered to the base layer, such that each gel is constrained substantially within a corresponding pocket disposed between the base layer and the covering layer. The adherent device further includes a circuit carrier holding electronic components electrically connected to the at least one electrode with the flexible circuit support to measure at least one physiologic signal of the subject.

In some embodiments, each of the gels and each of the pockets is sized larger than a corresponding opening of the stretchable base layer to retain said gel in said pocket when the stretchable base layer is adhered to the skin of the subject. In some embodiments, the stretchable base layer comprises a thin, flexible, stretchable base layer to stretch with the skin of the subject and conform to folds of the skin of the subject. In some embodiments, the stretchable covering layer comprises a thin, flexible, stretchable covering layer to stretch with the skin of the subject and conform to folds of the skin of the subject. The adherent device may further include a thin, flexible, stretchable overlayer disposed above and adhered to the covering layer. The overlayer may be made of woven fabric.

In some embodiments, the adherent device further comprises a stiffening structure disposed over and coupled to a common perimeter of the base and covering layers and configured to stiffen the perimeter edges of the base and covering layers. The stiffening structure may be configured to be removable after the adherent device is adhered to the subject. In some embodiments, the adherent device further comprises a thin, flexible, stretchable overlayer disposed above and adhered to the covering layer, and the stiffening structure is disposed over and coupled to a common perimeter of the base and covering layers and the overlayer, and the stiffening structure is configured to stiffen the perimeter edges of the base and covering layers and the overlayer. The adherent device according to these embodiments may further include a soft, flexible cover disposed over the circuit carrier and coupled at a common perimeter to the base and covering layers. The cover may comprise a material configured to inhibit liquids from reaching the electronic components. A perimeter of the cover may be disposed under the stiffening structure. In some embodiments, the flexible circuit is configured to be stretchable.

In some embodiments, the flexible circuit is formed of a substantially non-stretchable material, and is geometrically configured to be stretchable. In some embodiments, the flexible circuit comprises a polyester base and traces formed of silver conductive ink. The flexible circuit may comprise a serpentine shape. The flexible circuit may be disposed between the base layer and the covering layer.

In some embodiments, the adherent device further comprises a compliant connection between the circuit carrier and the base layer. In some embodiments, the combination of the base layer and the covering layer is breathable. The combination of the base layer and the covering layer may have a moisture vapor transmission rate of at least 100 $g/m^2/day$.

According to some embodiments, an adherent device comprises a thin, flexible, stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side. At least one electrode is affixed to the base layer and is capable of electrically coupling to the skin of a subject. A flexible circuit is connected to the at least one electrode, and a circuit carrier holding electronic components is electrically connected to the at least one electrode via the flexible circuit and configured to measure at least one physiologic signal of the subject. The adherent device further includes a stiffening structure disposed over and coupled to a perimeter of the base layer and configured to stiffen the perimeter edge of the base layer. In some embodiments, the stiffening structure is configured to be removable when the adherent device is adhered to the subject. The stiffening structure may be made from a vinyl sheet.

In some embodiments, the adherent device further comprises a thin, flexible, stretchable overlayer disposed above and adhered to the base layer, and the stiffening structure is disposed over and coupled to a common perimeter of the base layer and overlayer and is configured to stiffen the perimeter edge of the base layer and overlayer. According to some embodiments, the adherent device further includes a gel patch under each electrode, and each gel patch enhances electrical conductivity between its respective electrode and the skin of the subject. The flexible circuit is configured to be stretchable.

In some embodiments, the adherent device further comprises a soft, flexible cover disposed over the circuit carrier and coupled at a perimeter to the base layer. The cover may comprise a material configured to inhibit liquids from reaching the electronic components. The lower side of the base layer is configured to adhere to the skin of a subject.

In some embodiments, the adherent device further comprises a thin, flexible, stretchable underlayer adhered to the lower side of the base layer, the underlayer configured to adhere to the skin of the subject. The combination of the base layer and underlayer may be breathable. The combination of the base layer and underlayer may has a moisture vapor transmission rate of at least 100 $g/m^2/day$.

In some embodiments, the adherent device further comprises a gel patch under each electrode, and each gel patch enhances electrical conductivity between its respective electrode and the skin of the subject, and a perimeter of each gel patch is sandwiched between the base layer and the underlayer. In some embodiments, the underlayer comprises at least one opening through which electrical contact is made between the at least one electrode and the skin of the subject. The adherent device many further include a compliant connection between the circuit carrier and the base layer.

According to some embodiments, an adherent device comprises a thin, flexible, stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side. At least one electrode is affixed to the base layer and capable of electrically coupling to the skin of a subject. A flexible circuit is connected to the at least one electrode, and is configured to stretch. The adherent device further includes a circuit carrier holding electronic components electrically connected to the at least one electrode via the flexible circuit and configured to measure at least one physiologic signal of the subject.

In some embodiments, the flexible circuit is formed of a substantially non-stretchable material, and is geometrically configured to be stretchable. In some embodiments, the flexible circuit comprises a polyester base and traces formed of silver conductive ink. The flexible circuit may comprise a serpentine shape. The flexible circuit may comprise a sawtooth shape.

In some embodiments, the adherent device further comprises gel patch under each electrode, and each gel patch enhances electrical conductivity between its respective electrode and the skin of the subject. In some embodiments, the base layer is configured to adhere to the skin of the subject, and the adherent device further comprises a thin, flexible, stretchable overlayer disposed above and adhered to the base layer. In some embodiments, the adherent device further comprises a thin, flexible, stretchable underlayer disposed below and adhered to the base layer, and the underlayer is configured to adhere to the skin of the subject. In some embodiments the adherent device further comprises a stiffening structure disposed over and coupled to a perimeter of the base layer and configured to stiffen the perimeter edge of the base layer. The adherent device may comprise a compliant connection between the circuit carrier and the base layer.

According to some embodiments, an adherent device to monitor a subject having a skin comprises a stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side to adhere the base layer to the skin of a subject. The base layer has at least two openings extending therethrough, each of the at least two openings having a size. A stretchable covering layer is positioned above and adhered to the base layer with an adhesive to define at least two pockets. The adherent device further comprises a flexible circuit support that includes a first portion and a second portion, the first portion of the support adhered between the stretchable base layer and the stretchable covering layer, the second portion extending from the first portion. At least two electrodes are disposed on the first portion of the flex circuit support. The adherent device further includes at least two gels, and each gel and each electrode are positioned within a corresponding pocket, each gel having a size larger than the size of the respective opening to retain said gel substantially within said pocket between the base layer and the covering layer. The adherent device further includes a circuit carrier supported with the stretchable base layer, the circuit carrier holding electronic components electrically connected to the at least two electrodes with the second portion of the flexible circuit support to relieve strain when the stretchable base layer stretches with the skin of the subject, the electronic components configured to measure at least one physiologic signal of the subject.

According to some embodiments, a method of manufacturing an adherent device to adhere to a skin of a subject comprises providing a stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side to adhere the base layer to the skin of a subject. The base layer has at least two openings extending therethrough, each of the at least two openings having a size. The method further comprises providing a flexible circuit support having at least two electrodes and traces of electrically conductive material disposed thereon, providing at least two gels, and providing a stretchable covering layer. The method further comprises positioning the flexible circuit support and at least two gels between the stretchable base layer and the stretchable covering layer, and adhering the stretchable base layer to the stretchable covering layer to form at least two pockets, wherein each pocket has one of the at least two gels and one of the electrodes disposed therein. The method also includes coupling a circuit carrier to the at least two electrodes with the flexible circuit support.

According to some embodiments, a method of monitoring a patient having a skin comprises adhering a stretchable base layer affixed to a stretchable covering layer to the skin of the patient. The stretchable base layer and the stretchable covering layer define a plurality of pockets with gels and electrodes disposed therein and the electrodes are coupled to the skin with the gels disposed in the pockets. The method further comprises measuring signals from the electrodes to monitor the patient.

According to some embodiments, an adherent device to adhere to a skin of a subject comprises means for adhering to a skin of a subject, and a circuit carrier means coupled to the means for adhering to measure at least one physiologic signal of the subject.

Other embodiments are also described and claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a patient and a monitoring system comprising an adherent device, in accordance with embodiments of the present invention.

FIG. **2**A shows a partial exploded perspective view of an adherent device as in FIG. **1**, in accordance with embodiments of the invention.

FIG. **2**B illustrates an exploded view of a support patch, according to embodiments of the invention.

FIG. **2**C shows a bottom view of the support patch of FIG. **2**B.

FIG. **3** shows a flexible circuit that is configured to be stretchable, in accordance with embodiments of the invention.

FIG. **4** illustrates a compliant connection between a circuit carrier and a base layer, in accordance with embodiments of the invention.

FIG. **5** illustrates an exploded view of an adherent device in accordance with additional embodiments of the invention.

FIG. **6** illustrates an exploded oblique view of an adherent device in accordance with additional embodiments of the invention.

DETAILED DESCRIPTION OF THE INVENTION

Embodiments of the present invention relate to subject monitoring and/or therapy. Although embodiments make specific reference to monitoring impedance and electrocardiogram signals with an adherent device, the system methods and device described herein may be applicable to any application in which physiological monitoring and/or therapy is used for extended periods, for example wireless physiological monitoring for extended periods.

Embodiments of the present invention can be particularly well suited for use with an adherent device that comprises a support, for example a patch that may comprise stretchable tape, such that the support can be configured to adhere to the subject and support the electronics and sensors on the subject. The support may also be porous and breathable so as to allow water vapor transmission, for example as described U.S. Pat. Pub. No. 2009/0076363, the full disclosure of which is incorporated herein by reference and suitable for combination in accordance with some embodiments of the present invention described herein. The adherent device may comprise a cover and electronic components disposed on a carrier coupled to the support so as to provide strain relief, such that the support can stretch and flex with the skin of the subject. The embodiments described herein can be particularly useful to inhibit motion of the electronics circuitry carrier when the support stretches and flexes, so as to decrease localized loading of the support that may contribute to peeling. When forces are localized near an edge of the adherent device, for example when the carrier moves against a cover, the localized forces may cause peeling near the edge, and the embodiments described herein can inhibit such localized forces with a compliant structure that inhibits motion of the carrier relative to the support and also allows the support to stretch.

FIG. **1** shows an example subject, patient P, and a monitoring system **10**. Patient P comprises a midline M, a first side S**1**, for example a right side, and a second side S**2**, for example a left side. Monitoring system **10** comprises an adherent device **100**. Adherent device **100** can be adhered to a patient P at many locations, for example thorax T or arm A of patient P. In many embodiments, the adherent device may adhere to one side of the patient, from which side data can be collected. Work in relation with embodiments of the present invention suggests that location on a side of the patient can provide comfort for the patient while the device is adhered to the patient.

Monitoring system **10** includes components to transmit data to a remote center **106**. Remote center **106** can be located in a different building from a subject such as patient P, for example in the same town as the subject, and can be located as far from the subject as a separate continent from the subject, for example the subject located on a first continent and the remote center located on a second continent. Adherent device **100** can communicate wirelessly to an intermediate device **102**, for example with a single wireless hop from the adherent device on the subject to the intermediate device. Intermediate device **102** can communicate with remote center **106** in many ways, for example with an internet connection and/or with a cellular connection. In many embodiments, monitoring system **10** comprises a distributed processing system with at least one processor comprising a tangible medium on device **100**, at least one processor on intermediate device **102**, and at least one processor **106**P at remote center **106**, each of which processors can be in electronic communication with the other processors. At least one processor **102**P comprises a tangible medium **102**T, and at least one processor **106**P comprises a tangible medium **106**T. Remote processor **106**P may comprise a backend server located at the remote center. Remote center **106** can be in communication with a health care provider **108**A with a communication system **107**A, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Health care provider **108**A, for example a family member, can be in communication with patient P with a communication, for example with a two way communication system, as indicated by arrow **109**A, for example by cell phone, email, landline. Remote center **106** can be in communication with a health care professional, for example a physician **108**B, with a communication system **107**B, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Physician **108**B can be in communication with patient P with a communication, for example with a two way communication system, as indicated by arrow **109**B, for example by cell phone, email, landline. Remote center **106** can be in communication with an emergency responder **108**C, for example a **911** operator and/or paramedic, with a communication system **107**C, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Emergency responder **108**C can travel to the patient as indicated by arrow **109**C. Thus, in many embodiments, monitoring system **10** comprises a closed loop system in which patient care can be monitored and implemented from the remote center in response to signals from the adherent device.

In many embodiments, the adherent device may continuously monitor physiological parameters, communicate wirelessly with a remote center, and provide alerts when necessary. The system may comprise an adherent patch, which attaches to the subject's thorax and contains sensing electrodes, battery, memory, logic, and wireless communication capabilities. In some embodiments, the device can communicate with the remote center, via the intermediate device in the subject's home. In some embodiments, the remote center **106** receives the patient data and applies a patient evaluation and/or prediction algorithm. When a flag is raised, the center may communicate with the patient, hospital, nurse, and/or physician to allow for therapeutic intervention, for example to prevent decompensation.

In many embodiments, the adherent device may comprise a reusable electronics module with replaceable patches, and each of the replaceable patches may include a battery. The module may collect cumulative data for approximately 90 days and/or the entire adherent component (electronics+patch) may be disposable. In a completely disposable embodiment, a "baton" mechanism may be used for data transfer and retention, for example baton transfer may include baseline information. In some embodiments, the device may have a rechargeable module, and may use dual battery and/or electronics modules, wherein one module **101**A can be recharged using a charging station **103** while the other module **101**B is placed on the adherent patch with connectors. In some embodiments, the intermediate device **102** may comprise the charging module, data transfer, storage and/or transmission, such that one of the electronics modules can be placed in the intermediate device for charging and/or data transfer while the other electronics module is worn by the subject.

System **10** can perform the following functions: initiation, programming, measuring, storing, analyzing, communicating, predicting, and displaying. The adherent device may contain a subset of the following physiological sensors: bioimpedance, respiration, respiration rate variability, heart rate (ave, min, max), heart rhythm, heart rate variability (hereinafter "HRV"), heart rate turbulence (hereinafter "HRT"), heart sounds (e.g. S**3**), respiratory sounds, blood pressure, activity, posture, wake/sleep, orthopnea, temperature/heat flux, and weight. The activity sensor may comprise one or more of the following: ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise, posture. Additional details about the use of an adherent patch to measure particular physiologic signals may be found in co-pending U.S. patent application Ser. No. 12/209,273 (publication 2009/0076363) and Ser. No. 12/209,288 (publication 2009/0076345), both filed on Sep. 12, 2008 and titled "Adherent Device with Multiple Physiologic Sensors"

The adherent device can wirelessly communicate with remote center **106**. The communication may occur directly (via a cellular or Wi-Fi network), or indirectly through intermediate device **102**. Intermediate device **102** may consist of multiple devices, which can communicate wired **104** or wirelessly to relay data to remote center **106**.

In many embodiments, instructions are transmitted from remote site **106** to a processor supported with the adherent patch on the subject, and the processor supported with the subject can receive updated instructions for the subject treatment and/or monitoring, for example while worn by the subject.

In order for complete and reliable data to be gathered by system **10**, and for optimal subject comfort, it is desirable that adherent device **100** remain securely attached to subject for a predetermined period of time, for example one week, or two weeks or more. If adherent device **100** becomes dislodged prematurely, such that one or more of the sensing electrodes no longer makes secure contact with the subject's skin, valuable medical or other data may be lost. For example, a dislodged adherent device **100** may also need to be replaced, causing discomfort for a patient, inconvenience for medical personnel, and unwanted expense.

Various adhesion failure mechanisms have been noted. Normal subject activity may result in adherent device **100** being stretched, bumped, jostled, or otherwise moved in a way that tends to stress the adhesive joint with the subject's skin. This may be especially true for an adherent device that is worn for a long period of time, during which the subject may wish to carry on normal activities, including exercise, bathing, and the like. The edges of the support patch may be especially prone to separation from the skin, and may form pathways for ingress of moisture, which can accelerate the deterioration of the adhesive bond between the adherent device and the skin. The difficulty of maintaining a secure bond to the subject's skin may be further exacerbated as it becomes desirable to add new features and capabilities to a device such as adherent device **100**. For example, in order to extend the working life of adherent device **100** or to provide sophisticated features, it may be desirable to include a battery having considerable weight, and additional electronics or packaging as compared with previous designs. The combined weight of the battery and electronics may be as much as 60 grams or more, such that jostling of the unit may impart significant inertial loads on the bond with the subject's skin. In addition, the position of the adherent device may affect the durability of the adhesive bond with the subject's skin. For example, especially useful electrocardiogram readings may be obtained by a device placed between a patient's left clavicle and left nipple. However, this area is also prone to stretching, and may present a difficult site for long-term adhesion. Even if an alternative site is used, for example along the patient's rib line, enhanced adhesion durability is desirable.

In addition to the medical setting described above, embodiments of the present invention may also be used in non-medical settings, and on subjects other than human medical patients. For example, an adherent device according to embodiments of the invention may be used to monitor the heart rate or other data of an athlete during exercise. In another setting, an adherent device according to embodiments of the invention may be used to monitor an animal for agricultural research, veterinary medical testing or treatment, or other purposes. For the purposes of this disclosure, a subject is any human or animal to which an adherent device according to embodiments of the invention may be adhered, for any purpose. While certain example uses of adherent devices are described herein in relation to monitoring or treatment of a medical patient, the appended claims are not so limited. Whatever the setting or subject, embodiments of the present invention provide improved durability of the adhesive bond between the adherent device and the subject's skin, as compared with prior adherent devices.

FIG. **2**A shows a partial exploded perspective view of adherent device **100** as in FIG. **1**, in accordance with embodiments of the invention. Adherent device **100** comprises a support patch **201**, which may further comprise a base layer **202** and a covering layer **203**. Base layer **202** is stretchable, and has an upper side **204** and a lower side **205**, and an adhesive coating on lower side **205** to adhere base layer **202** to the skin of a subject. Covering layer **203** is also stretchable, and is positioned above and adhered to base layer **202**. FIG. **2**B illustrates an exploded view of support patch **201**, according to embodiments of the invention. As is best seen in FIG. **2**B, a flexible circuit **206** includes at least two electrodes, for example electrodes **207**A, **207**B, **207**C, and **207**D that during use are in electrical contact with the skin of the subject. Flexible circuit **206** may also sometimes be called a flexible circuit support. Flexible circuit **206** electrically connects electrodes **207**A, **207**B, **207**C, and **207**D to a circuit carrier **208**, which holds electronic components **209** configured to measure at least one physiologic signal of the subject. Electronic components **209** may include an antenna **210** so that adherent device **100** can communicate its readings for remote monitoring. Circuit carrier **208** may be mechanically connected to and supported by base layer **202** by any suitable means, including those discussed in more detail below.

Adherent device **100** may further comprise a housing **211** that fits over electronic components **209**, providing protection, insulation, and cushioning for electronic components **209**. Housing **211** may further include features for holding a battery **212**. Housing **211** may be made, for example of a soft silicone rubber. In other embodiments, housing **211** may comprise an encapsulant over electronic components **209** and circuit carrier **208**. Housing **211** may provide protection of electronic components **209** from moisture.

Adherent device **100** may also comprise a cover **213** adhered to support patch **201**. Cover **213** may comprise any known biocompatible cover, casing and/or housing materials, such as elastomers, for example silicone. The elastomer may be fenestrated to improve breathability. In some embodiments, cover **213** may comprise other breathable materials, for example a cloth including polyester, polyamide, nylon and/or elastane (Spandex™). The breathable fabric may be coated or otherwise configured to make it water resistant, waterproof, for example to aid in wicking moisture away from the patch, or to inhibit liquids from reaching electronic components **209**.

While adherent device **100** is shown as generally oblong and having a length of about two to three times its width, this is not a requirement. One of skill in the art will recognize that other shapes are possible for an adherent device according to embodiments of the invention. For example, support patch **201** could be round, elliptical or oblong with a length only slightly larger than its width, square, rectangular, or some other shape. And while electrodes **207**A, **207**B, **207**C, and **207**D are illustrated as being arranged linearly, this is also not a requirement. One of skill in the art will recognize that electrodes **207**A, **207**B, **207**C, and **207**D could be arranged in any pattern suitable for the intended use of adherent device **100**, including in a circular, oblong, square, rectangular, or other pattern.

Referring again to FIG. **2**B, base layer **202** includes at least two openings, in this case four openings **215**A, **215**B, **215**C, and **215**D, each corresponding to one of electrodes **207**A, **207**B, **207**C, and **207**D. Each opening is of a certain size. Gels **214**A, **214**B, **214**C, and **214**D are placed at the openings, between base layer **202** and covering layer **203**. Each of gels **214**A, **214**B, **214**C, and **214**D comprises a hydrogel patch of electrically conductive gel material that enhances electrical conductivity between its respective electrode and the skin of the subject. For example, the gels **214**A, **214**B, **214**C, and **214**D may be made of hydrogel adhesive 9880 available from the 3M Company of St. Paul, Minn., USA, or another suitable material.

Each of gels **214**A, **214**B, **214**C, and **214**D is larger than its respective opening **215**A, **215**B, **215**C, or **215**D, such that when covering layer **203** and base layer **202** are adhered together, a pocket is formed over each of openings **215**A, **215**B, **215**C, and **215**D, with one of gels **214**A, **214**B, **214**C, and **214**D retained in each respective pocket.

Preferably, base layer **202**, covering layer **203**, or both are thin, flexible, and stretchable to stretch with the skin of the subject and conform to folds of the skin of the subject. For example, either or both of these layers may be made of MED 5021 polyurethane film available from Avery Dennison Corporation of Pasadena, Calif., USA, or Tegaderm™ film available from the 3M Company of St. Paul, Minn., USA. Other suitable materials may be used.

In some embodiments, support patch **201** may further include an overlayer **216** disposed above and adhered to covering layer **203**. Overlayer **216** is also preferably thin, flexible, and stretchable. For example, overlayer **216** may be made of a woven fabric.

Referring again to FIG. **2**A, gels **214**A, **214**B, **214**C, and **214**D are preferably placed under covering layer **203** (and overlayer **216**, if present). Flexible circuit **206** may also be positioned under covering layer **203**, as indicated by the broken line depiction of part of flexible circuit **206** in FIG. **2**B. Gels **214**A, **214**B, **214**C, and **214**D may thus be retained in pockets between base layer **202** and covering layer **203**.

Adherent device **100** may further comprise a stiffening structure such as stiffening structure **217** shown in FIG. **2**A. In this example embodiment, stiffening structure **217** is configured to adhere to the top of cover **213**, at an outer area **218** of cover **213**. As assembled, stiffening structure **217** is then coupled to a common perimeter of the base and covering layers, so that the perimeter edges of the base and covering layers are stiffened, for example to prevent curling or unintentional adhesion of the lower side **205** of base layer **202** to itself. Stiffening structure **217** may be made of a material that is stiffer than the materials used in base patch **201**, but still compliant enough to allow base patch **201** to conform to the subject's skin as the patch is adhered to the skin. For example, stiffening structure **217** may be made from a vinyl sheet. Stiffening structure **217** may also be configured to be removable after adherent device **100** is adhered to the subject's skin. For example, stiffening structure **217** may include an adhesive configured to hold stiffening structure **217** in place during application of adherent device **100** to the subject, but to release easily without dislodging adherent device **100** from the subject's skin. In this way, stiffening structure **217** may aid in achieving a secure adhesion of adherent device **100** to the subject, but not interfere with the ability of support patch **201** to conform to wrinkles, folds, and other movements of the subject's skin while adherent device **100** is worn.

FIG. **2**C shows a bottom view of support patch **201**, with bottom lower side **205** of base layer **202** visible. Also visible are openings **215**A, **215**B, **215**C, and **215**D, exposing portions of gels **214**A, **214**B, **214**C, and **214**D. Other portions of gels **214**A, **214**B, **214**C, and **214**D are behind base layer **202**, in pockets formed between base layer **202** and covering layer **203**.

In some embodiments, flexible circuit **206** may be made of a flexible material such as polyimide, polyester, or another base material, having circuit traces formed in or on the base material. The circuit traces may be, for example, made of copper, a copper alloy, silver ink, or another conductive material. In one preferred embodiment, flexible circuit **206** comprises a polyester base and traces formed of silver conductive ink. In some embodiments, flexible circuit **206** may be configured to be stretchable, as well as flexible. Even if the material of the flexible circuit **206** is not inherently stretchable, the flexible circuit may be made effectively stretchable by properly configuring its geometric shape. For example, at least the portion of flexible circuit **206** in contact with support patch **201** may have a serpentine shape that allows support patch **201** to stretch and conform itself to the skin of the subject to which adherent device **100** is adhered, without being unduly constrained by flexible circuit **206**. A flexible circuit **206**A having this characteristic is shown in FIG. **3**. Other configurations may be used as well. For example, flexible circuit **206**A may have a sawtooth shape, or another shape that enables stretching of the flexible circuit **206**A.

As was mentioned previously, circuit carrier **208** may have a compliant connection to base layer **202**. One exemplary kind of compliant connection is illustrated in FIG. **4**. In this connection, bridging loops **401**A, **401**B, **401**C, and **401**D connect from support patch **201** (which includes base layer **202**) to circuit carrier **208**. Loops **401**A, **401**B, **401**C, and **401**D may be made, for example, of a plastic reinforced paper, a plastic film, a fabric, metal, or any other suitable material. Preferably, loops **401**A, **401**B, **401**C, and **401**D permit relatively free rotation of circuit carrier **208** about the X and Y axes illustrated in FIG. **4**, but constrain the rotation of circuit carrier **208** about the Z axis. Because each of loops **401**A, **401**B, **401**C, and **401**D connects to support patch **201** at an inner portion **402** rather than at an outer portion **403** of support patch **201**, loads imparted to support patch **201** tend not to disturb the vulnerable perimeter of support patch **201**, where detachment from the subject's skin is especially likely to start. More detail about compliant connections between circuit carrier **208** and base layer **202** may be found in copending provisional U.S. patent application 61/241,713, filed Sep. 11, 2009 and titled "Electronics Integration in Adherent Patch for Physiologic Monitoring", the entire disclosure of which is hereby incorporated by reference for all purposes.

In some embodiments, base layer **202**, covering layer **203**, or their combination may be breathable. For example, the combination of base layer **202** and covering layer **203** may have a moisture vapor transmission rate of at least 100 g/m^2/day.

FIG. **5** illustrates an exploded view of an adherent device **500** in accordance with additional embodiments of the invention. Adherent device **500** includes several components similar to those in adherent device **100**, and similar components are given the same reference numbers in FIG. **5**. Adherent device **500** may include different combinations of layers than adherent device **100**.

Adherent device **500** comprises a support patch **501** that includes a base layer **502**. Base layer **502** has an upper side **504** and a lower side **505**. Lower side **505** includes an adhesive coating. At least one electrode, in this example four electrodes **207**A, **207**B, **207**C, and **207**D are affixed to base layer **502** and connected to flexible circuit **206**. Besides being flexible, flexible circuit **206** may also be configured to be stretchable, for example due to its geometric configuration. In some embodiments, a portion of flexible circuit **206** may have a serpentine or sawtooth shape. Circuit carrier **208** holds electronic components **209**, which may include an antenna **210**. Electronic components **209** are electrically connected to electrodes **207**A, **207**B, **207**C, and **207**D and are configured to measure at least one physiologic signal of a subject to which adherent device **500** is adhered.

A stiffening structure **217** may be disposed over and coupled, directly or indirectly, to a perimeter area of base layer **502**, to stiffen the perimeter edge of base layer **502**. In some embodiments, a cover **213** is disposed over circuit carrier **208** and coupled at a perimeter **218** to base layer **502**. In that case, stiffening structure **217** is disposed over and coupled to cover **213**, and is therefore indirectly coupled to base layer **502**. Cover **213** is preferably soft and flexible, and may be made of a material configured to inhibit liquids from reaching electronic components **209**.

Similarly, in some embodiments, an overlayer **503** may be disposed above and adhered to base layer **502**. Overlayer **503** is preferably thin, flexible, and stretchable, and may be made of a woven cloth or another suitable material. When overlayer **503** is present, stiffening structure **217** is also disposed over and coupled to the perimeter of overlayer **503**, and stiffens at least the perimeter edges of the base layer and overlayer. All of the layers of a support patch such as support patch **501** or support patch **201** may be coextensive, having their edges aligned as was shown in FIG. **2**C. Alternatively, one or more layers in a support patch may not be coextensive with the others. For example, overlayer **503** is slightly smaller than base layer **502**, so that the edges of base layer **502** extend beyond the edges of overlayer **503**. This arrangement may further reduce the stresses on the edge of base layer **502**, thus promoting long adhesion to the subject to which adherent device **500** is adhered. This arrangement may be used in any of the embodiments described herein.

Adherent device **500** may comprise one or more gel patches **214**A, **214**B, **214**C, and **214**D, one gel disposed under each of electrodes **207**A, **207**B, **207**C, and **207**D. Gel patches **214**A, **214**B, **214**C, and **214**D enhance electrical conductivity between electrodes **207**A, **207**B, **207**C, and **207**D and the skin of a subject to which adherent device **500** is adhered.

In some embodiments, lower side **505** of base layer **502** is configured to adhere to the skin of a subject. In that configuration, gel patches **214**A, **214**B, **214**C, and **214**D are captured between base layer **502** and the subject's skin. Optionally, an underlayer **506** may be provided, adhered to lower side **505** of base layer **504**, and configured to adhere to the skin of a subject. Preferably, underlayer **506** is also thin, flexible, and stretchable. For example, base layer **202**, underlayer **506**, or both may be made of MED 5021 polyurethane film available from Avery Dennison Corporation of Pasadena, Calif., USA, or Tegaderm™ film available from the 3M Company of St. Paul, Minn., USA. Other suitable materials may be used. Underlayer **506** may comprise openings **215**A, **215**B, **215**C, and **215**D, and may capture gels **214**A, **214**B, **214**C, and **214**D in pockets formed between base layer **502** and underlayer **506**.

As in adherent device **100**, adherent device **500** may include a compliant connection between circuit carrier **208** and base layer **502**, for example a compliant connection as shown in FIG. **4** and described previously.

FIG. **6** illustrates an exploded oblique view of an adherent device **600** in accordance with additional embodiments of the present invention. In this embodiment, a support patch **601** may be configured to adhere to a subject's skin, and may be a support patch as in any of the embodiments described above. Support patch **601** may include a base layer, a covering layer, an overlayer, an underlayer, or any workable combination of these. Support patch **601** may include one or more electrodes (not visible in FIG. **6**) electrically connected to a flexible circuit **206**. A label **610** may be affixed to support patch **601**. A circuit carrier **208** holds various electronic components **209**, which may include a processor, memory, wireless communication circuitry, an antenna **210**, and other electronic components. Adherent device **600** may also include a temperature or heat flux sensor **602**. Bridging loops **603**A, **603**B, **603**C (and a fourth bridging loop not visible in FIG. 3B) are affixed to support patch **201** and to circuit carrier **208**, and form a compliant structure that compliantly restrains motion of circuit carrier **208** with respect to support patch **601** in some degrees of freedom more stiffly than in other degrees of freedom. A housing **604** and protector **605** may insulate, cushion, or otherwise protect circuit carrier **208**. The adherent device may further comprise a battery **606** or other energy source, a battery cover **607**, a cover **608**, and a display **609**.

While exemplary embodiments have been described in some detail, by way of example and for clarity of understanding, those of skill in the art will recognize that a variety of modifications, adaptations, and changes may be employed. Hence, the scope of the present invention should be limited solely by the appended claims.

What is claimed is:

1. An adherent device to adhere to a skin of a subject, comprising: a stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side to adhere the base layer to the skin of the subject, the base layer having at least two openings extending therethrough, each of the at least two openings having a size; a stretchable covering layer positioned above and adhered to the base layer with an adhesive to define at least two pockets, wherein the stretchable covering layer is thin, flexible, and configured to stretch with the skin of the subject; at least two gels, wherein each gel is positioned within one of the corresponding pockets, each gel having a size larger than the size of the at least two openings to retain said gel substantially within said corresponding pocket; a flexible circuit that includes at least two electrodes in contact with the at least two gels, the flexible circuit including a first portion located on the upper side of the stretchable base layer and a second portion that extends away from the first portion and through an opening in the stretchable covering layer; a circuit carrier positioned above the stretchable covering layer and supported with the stretchable base layer to measure at least one physiologic signal of the subject, wherein the circuit carrier is connected to the at least two electrodes via the second portion extending through an opening in the stretchable covering layer; and a compliant connection that includes a plurality of bridging loops formed between the upper side of the stretchable base layer and the circuit carrier that permits at least some movement of the circuit carrier in a plane parallel to the stretchable base layer.

2. An adherent device to monitor a subject having a skin, comprising: a stretchable base layer having an upper side and a lower side and an adhesive coating disposed on the lower side to adhere the base layer to the skin of the subject, the base layer having at least two openings extending therethrough, each opening having a size; a flexible circuit having at least two electrodes disposed thereon, each electrode positioned with a respective one of the at least two openings to couple to the skin of the subject the flexible circuit including a first portion located adjacent to the upper side of the stretchable base layer and a second portion that extends away from the stretchable base layer through an opening in a stretchable covering layer; at least two gels positioned with the at least two openings in the base layer, each gel having a size larger than the size of said each opening; the stretchable covering layer positioned above the at least two gels and adhered to the base layer, such that each gel is constrained substantially within a corresponding pocket disposed between the base layer and the covering layer, wherein the stretchable covering layer is thin, flexible, and configured to stretch with the skin of the subject; a circuit carrier positioned above the stretchable covering layer and holding electronic components electrically connected to the at least one electrode via the second portion of with the flexible circuit to measure at least one physiologic signal of the subject; and a compliant connection that includes a plurality of bridging loops formed between an upper side the stretchable base layer and the circuit carrier that permits at least some movement of the circuit carrier in a plane parallel to the stretchable base layer.

3. The adherent device of claim **2** wherein each of the gels and each of the pockets is sized larger than a corresponding opening of the stretchable base layer to retain said gel in said pocket when the stretchable base layer is adhered to the skin of the subject.

4. The adherent device of claim **2** wherein the stretchable base layer comprises a thin, flexible, stretchable base layer to stretch with the skin of the subject and conform to folds of the skin of the subject, and wherein the stretchable covering layer is configured to conform to folds of the skin of the subject.

5. The adherent device of claim **2**, further comprising a thin, flexible, stretchable overlayer disposed above and adhered to the covering layer.

6. The adherent device of claim **2**, wherein the first portion of the flexible circuit is formed of a substantially non-stretchable material, and has a serpentine, sawtooth, or other shape that geometrically configures the flexible circuit to be stretchable along a length of the adherent device.

7. The adherent device of claim **2**, wherein the first portion of the flexible circuit is disposed between the base layer and the covering layer.

8. An adherent device, comprising:

a thin, flexible, stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side to adhere to the skin of a subject;

at least one electrode affixed to the base layer and capable of electrically coupling to the skin of the subject;

a flexible circuit connected to the at least one electrode, wherein the flexible circuit includes a first portion located adjacent to the upper side of the stretchable base layer and a second portion that extends away from the first portion, wherein the second portion of the flexible circuit includes a loop shape to relieve strain when the stretchable base layer stretches with the skin of the subject;

a circuit carrier holding electronic components electrically connected to the at least one electrode via the second portion of the flexible circuit and configured to measure at least one physiologic signal of the subject;

a compliant connection that includes a plurality of loops formed between the upper side of the stretchable base layer and the circuit carrier that permits at least some movement of the circuit carrier in a plane parallel to the stretchable base layer, wherein the second portion of the flexible circuit extends around an outer circumference of one of the plurality of loops; and

a stiffening structure disposed above and coupled to a perimeter of the base layer and configured to stiffen the perimeter edge of the base layer, wherein the stiffening structure is removable.

9. The adherent device of claim 8, further comprising a thin, flexible, stretchable overlayer disposed above and adhered to the base layer, the stiffening structure disposed over and coupled to a common perimeter of the base layer and overlayer and configured to stiffen the perimeter edge of the base layer and overlayer.

10. The adherent device of claim 8, further comprising a gel patch under each electrode, wherein each gel patch enhances electrical conductivity between its respective electrode and the skin of the subject.

11. The adherent device of claim 8, wherein the flexible circuit is configured to be stretchable.

12. An adherent device, comprising:

a thin, flexible, stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side configured to adhere to a skin of a subject;

at least one electrode affixed to the base layer and capable of electrically coupling to the skin of a subject;

a flexible circuit having a first portion located on the upper side of the stretchable base layer that is connected to the at least one electrode and a second portion that extends away from the stretchable base layer, wherein the first portion of the flexible circuit is formed of a substantially non-stretchable material, and has a serpentine, sawtooth, or other shape that geometrically configures the flexible circuit to be stretchable along a length of the adherent device, and wherein the second portion includes a loop shape to relieve strain when the stretchable base layer stretches with the skin of the subject;

a circuit carrier positioned above and coupled to the flexible circuit, the circuit carrier holding electronic components electrically connected to the at least one electrode via the second portion of the flexible circuit flexible circuit and configured to measure at least one physiologic signal of the subject; and

a compliant connection formed between the stretchable base layer and the circuit carrier that permits at least some movement of the circuit carrier in a plane parallel to the stretchable base layer.

13. The adherent device of claim 12, further comprising a gel patch under each electrode, wherein each gel patch enhances electrical conductivity between its respective electrode and the skin of the subject.

14. The adherent device of claim 12, further comprising a thin, flexible, stretchable overlayer disposed above and adhered to the base layer.

15. An adherent device to monitor a subject having a skin, comprising:

a stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side to adhere the base layer to the skin of a subject, the base layer having at least two openings extending therethrough, each of the at least two openings having a size;

a stretchable covering layer positioned above and adhered to the base layer with an adhesive to define at least two pockets, wherein the stretchable covering layer is thin, flexible, and configured to stretch with the skin of the subject;

a flexible circuit comprising a first portion and a second portion, the first portion of the flexible circuit adhered between the stretchable base layer and the stretchable covering layer, the second portion having a loop shape that extends away from the first portion through an opening in the stretchable covering layer, wherein the first portion of the flexible circuit is formed of a substantially non-stretchable material, and has a serpentine, sawtooth, or other shape that geometrically configures the flexible circuit to be stretchable along a length of the adherent device;

at least two electrodes in contact with the first portion of the flexible circuit;

at least two gels, wherein each gel and each electrode are positioned within a corresponding pocket, each gel having a size larger than the size of the respective opening to retain said gel substantially within said pocket between the base layer and the covering layer; and

a circuit carrier positioned above the stretchable covering layer and supported with the stretchable base layer, the circuit carrier holding electronic components electrically connected to the at least two electrodes with the second portion of the flexible circuit to relieve strain when the stretchable base layer stretches with the skin of the subject, the electronic components configured to measure at least one physiologic signal of the subject.

16. An adherent device to adhere to a skin of a subject, comprising:

means for adhering to a skin of a subject, the means for adhering comprising a stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side to adhere the base layer to the skin of a subject, the base layer having at least two openings extending therethrough, each of the at least two openings having a size, and the means for adhering further comprising a stretchable covering layer positioned above and adhered to the base layer with an adhesive to define at least two pockets, wherein the stretchable covering layer is thin, flexible, and configured to stretch with the skin of the subject;

a flexible circuit coupled to the means for adhering, the flexible circuit carrying at least two electrodes disposed on the flexible circuit and positioned to couple to the subject's skin, wherein the flexible circuit further includes a first portion located adjacent to the upper side of the stretchable base layer and a second portion that extends away from the flexible circuit and through an opening in the stretchable covering layer; and

means for enhancing electrical conductivity between the electrodes and the subject's skin,

a circuit carrier positioned above the stretchable covering layer and coupled to the at least two electrodes via the second portion of the flexible circuit, the circuit carrier holding circuitry to measure at least one physiologic signal of the subject; and

a compliant connection that includes a plurality of loops formed between the stretchable base layer and the circuit carrier that permits at least some movement of the circuit carrier in a plane parallel to the stretchable base layer.

17. The adherent device of claim **1**, wherein the base layer, the adhesive coating, and the covering layer are coextensive.

18. The adherent device of claim **2**, wherein the base layer, the adhesive coating, and the covering layer are coextensive.

19. The adherent device of claim **2**, wherein the circuit carrier and the electronic components are comprised in a reusable electronics module.

20. The adherent device of claim **1**, wherein the second portion of the flexible circuit includes a loop shape that extends around an outer circumference of one of the plurality of bridging loops.

21. The adherent device of claim **20**, wherein the plurality of bridging loops connect to an inner portion of the stretchable base layer to prevent loads from being transferred to a perimeter of the stretchable base layer.

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